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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,004	06/18/2003	Graham Edmund Kelly	7579.0015-01000	6037

22852 7590 06/29/2006

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,004	KELLY ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,28-35 and 41-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,28-35 and 41-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *05/16/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The following is responsive to the request for continued examination, accompanying amendment and the petition to delete originally named inventor under 37 CFR 1.48(b) all received May 16, 2006.

Claims 1-18, 19-20, 22-27, 36-40, 44-45 are cancelled. No new claims are added. Claims 21, 28-35, 41-43 are currently pending.

Petition to Correct Inventorship

Applicant's petition to correct inventorship under 37 CFR 1.48(b) received May 16, 2006 has been considered and will be entered. Accordingly, the Kelly et al. patent 6, 340,703 is no longer available as prior art by another.

New Ground(s) of Rejection

Claim Rejection(s)—35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 28 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 recites the limitation "treatment or prevention of osteoporosis" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 31 recites the limitation "said dosage form" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 21, 28-35, 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly WO 93/23069 in view of Empie et al., 6,261 ,565 B1 (both references already of record in parent file).

Kelly '069 discloses compositions enriched with phyto-estrogens selected from genistein, daidzein, formononetin and Biochanin A. These phyto-estrogens may be used as food additives or may be formulated into medicaments, i.e. tablets or capsules or powders, suspensions, or syrups, for promoting health in cases of cancer, pre- menstrual syndrome, menopause or hypercholesterolemia. Specifically, the compositions contain an excipient, diluent or carrier or may be mixed with food (drinks) or can be consumed directly. The phyto-estrogens may be obtained from red clover or subterranean clover or from soya. Other sources of the

phytoestrogens include chick peas. Moreover, it is preferred that the ratio of genistein and/or Biochanin A to daidzein and/or formononetin is between 1:2 to 2:1. Finally, the compositions may be formulated along with vitamin supplements. Please see the abstract page 8 to page 9, line 1; page 10, line 19; page 11, third full paragraph; page 13, last line to page 14, line 7.

Kelly '069 does not specifically disclose using the compositions for treating osteoporosis or bone fractures; however, the Examiner refers to Empie et al., which disclose compositions prepared by extracting phytochemicals from soy or red clover, wherein the resulting composition comprises isoflavones consisting predominantly of genistein and/or Biochanin A and/or formononetin with a ratio of genistein to daidzein from 100:1 to 1:100. Please see the abstract; col. 4, lines 44-55. Empie et al. additionally disclose that isoflavones are known to be useful in treating osteoporosis. Moreover, people who eat a diet high in soy show reduction of various symptoms discussed above, thus suggesting that ingesting a combination of these isoflavones at certain ratio such as that found in soy may result in an additive or synergistic effect. Please see col. 1, lines 39-43; col. 2, lines 25-53.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods and compositions of Kelly '069 for use in treating osteoporosis, because in view of Empie et al.'s teachings, one of ordinary skill in the art would reasonably expect the substantially similar isoflavone containing compositions of Kelly '069 to be effective in treating such a disorder. Such a modification would have been motivated by the reasonable expectation of producing a nutritional composition capable of effectively treating disorders, i.e. osteoporosis, already known to respond to treatment by administration of isoflavones.

Concerning the claims drawn to treating or preventing bone fracture, this would have been obvious from the methods of the prior art because one of ordinary skill in the art would reasonably expect that treatment of osteoporosis would serve to reduce the likelihood of bone fractures.

Finally, with respect to the claimed ratios, since Kelly '069 and Empie et al. have established that the therapeutic efficacy of the isoflavones is dependent upon their ratio amounts, it would have been obvious to one of ordinary skill in the art to further modify the methods and compositions of Kelly and Empie et al. such that the isoflavones are present in a ratio that is effective to optimize their therapeutic activity.

Response to Applicant's Amendment(s)

Applicant's arguments pertaining to the substance of the previous claim rejection under 35 USC 103(a), Applicant contends that neither the Kelly publication '069 nor the Empie '565 patent discloses or fairly suggests the claimed inventions. Both references fail to teach high proportions of formononetin. In fact, applicant argues that both references teach away from the claimed high proportions of formononetin.

Concerning the Kelly '069 reference, applicant contends that the reference states that the ratio of genistein to daidzein is between 1:2 to 2:1 but does not provide a teaching of a ratio containing high proportions of formononetin. Additionally, Kelly '069 makes clear that it does not matter whether or not formononetin or its demethylated form, daidzein, is present. The Examiner is referred to the specification, page 10. In fact, Kelly '069 discloses that it is prudent that both genistein and daidzein be present in the claimed product in approximately equal

proportions. Finally, Kelly '069 is silent with respect to the use of the disclosed compositions for treating bone maladies.

Empie, the '565 patent, similarly teaches away from "high proportions of formononetin." Its background section concludes with the express proposition that "a need exists for an improved composition consisting substantially of isoflavones, lignans, saponogenins, saponins, and/or phenolic acids which will produce improved results over any of these taken alone." Col. 3, lines 31-34 (emphasis added). Furthermore, the Detailed Description begins by teaching that "the improved composition is obtained by fractionating a plant source high in isoflavones, lignans, and other phytochemicals. . .," col. 4, lines 16-18, and than later provides proportions for these mixtures, as follows: "the resulting composition is expected to comprise in a preferred from (sic) : between 5% and 95% isoflavones, between 0% and 70% lignans, and between 2% and 70% saponins and sapogenins. Col. 4, lines 44-47.

The paragraph does discuss a ratio of the derivatives of genistein (and/or its precursor biochanin) to derivatives of daidzein (and/or its precursor formononetin) of from 100:1 to 1:100, but that range merely covers the entire spectrum. And none of the isoflavone-based compositions made in Examples 1-4 indicate the amounts of the specific isoflavones. The separate solutions in Example 5 were made merely to test solubility and do not even include one based on formononetin.

Said arguments have been considered but are not found to be persuasive.

The Examiner respectfully maintains that the combination of references renders obvious applicant's claims. Concerning the claimed ratios having a high proportion of formononetin, the Examiner respectfully maintains since Kelly '069, as well as Empie et al. have established that

the therapeutic efficacy of the isoflavones is dependent upon their ratio amounts, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the methods and compositions of the prior art such that formononetin and biochanin or genistein or daidzein are present in a ratio that is effective to optimize their therapeutic activity.

Moreover, the court has held "it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 105 USPQ 233, 235 (CCPA 1955). Only if "the results of optimizing a variable are 'unexpectedly good' can a patent be obtained for a claimed critical range." In re Antonie, 195 USPQ 6, 8 (CCPA 1977). See also In re Geisler, 43 USPQ2d 1362 (CAFC 1997). Therefore, the Examiner respectfully submits, in view of Empie and Kelly '069 disclosure, and absent evidence of unexpected results, it would have been prima facie obviousness to arrive at the claimed ratios.

Conclusion

Claims 21,28-35 and 41-43 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Ardin Marschel**, can be reached on **571-272-0718**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
June 26, 2006

Cybille Delacroix-Muirheid
Patent Examiner Group 1600